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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,711	01/12/2004	Deborah Kim Glencross	025455-113	1340

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EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/754,711	GLENCROSS, DEBORAH KIM	
	Examiner	Art Unit	
	Allison M Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 and 5, drawn to a method of enumerating the number of CD 4 cells in a cell sample, classified in class 702, subclass 21.

II. Claims 3 and 4, drawn to a method for identifying a 5-part lymphocyte sub-set differential, classified in class 435, subclass 2.

III. Claims 6- 8, drawn to a kit comprising antibodies to CD 4 and CD 45, classified in class 530, subclass 387.1.

IV. Claims 9-11, drawn to a machine-readable medium, classified in class 710, subclass 1.

V. Claims 12 and 13, drawn to a method of monitoring the immune status of a patient with HIV or another immune deficiency disease, classified in class 424, subclass 9.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are distinct inventions and thus are subject to restriction. The inventions are distinct processes in that the methods are not dependent on each other, not to be used together and have different functions, modes of operation, and effects. In the instant case the method of Group I requires the enumeration of CD4 cells and CD45 cells in a cell sample by counting the number of CD45 cells and determining, by proportion, the number of CD4 cells. The method of Group II requires antibodies to CD4 and CD45, which are not required or described in the method of Group I. Additionally, the method of Group II requires the use of fluorescence detection, which is not required by the method of Group I. Therefore, though claim 3 (Group II) claims dependence from claim 1 (Group I), the methods are not commensurate in scope and are not related, as they comprise very different methodologies. A search and examination of the method of Group I would not overlap for the search of the method of Group II because each method has different steps, different effects, and very different scopes. The method of Group I

relates to cell enumeration, and is limited to proportional relationships between CD4 and CD45 cells; wherein the method of Group II does not require the enumeration of CD4 or CD45 cells, but rather requires CD4 and CD45 antibodies to perform immunological assays requiring fluorescence detection.

Inventions I and V are distinct inventions and thus are subject to restriction. The inventions are distinct processes in that the methods are not dependent on each other, not to be used together and have different functions, modes of operation, and effects. In the instant case the method of Group I requires the enumeration of CD4 cells and CD45 cells in a cell sample by counting the number of CD45 cells and determining, by proportion, the number of CD4 cells. The method of Group V is directed to monitoring the immune status of a patient with HIV or another immune deficiency condition or disease. The two methods are directed to different populations and are thus distinct. The method of Group I can be performed on any blood cell sample from the general population; however the method of Group V is restricted to only the population comprising patients with HIV or another immune deficiency condition. Though patients with HIV or another immune deficiency condition or disease are part of the general population, methods directed to this specific population require special modifications and considerations that merit it a distinct method.

Similarly, inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of Group II requires the use of CD4 and CD45 antibodies, which is not required in the method of Group V. Additionally, the method of Group II requires the use of fluorescence detection, which is not required by the method of Group II. Still further, the method of Group II can be performed on any blood sample from the general population; however the method of Group V is restricted to only the population comprising patients with HIV or another immune deficiency condition. Though patients with HIV or another

immune deficiency condition or disease are part of the general population, methods directed to this specific population require special modifications and considerations that merit it a distinct method.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed to be used together. The kit of Group III contains antibodies to CD4 and CD45, the method of Group I does not require antibodies; therefore the method of Group I cannot be performed using the kit of Group III.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit of Group III that comprises antibodies can be used for different processes than that of Group II. For example, the antibodies in the kit of Group III can alternatively be bound to magnetic beads and used to separate CD4 and/or CD45 cells from a cell sample.

Inventions IV and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed to be used together. The kit of Group III contains antibodies to CD4 and CD45, the computer readable medium does not contain or make use of antibodies, they are completely incompatible.

Similarly, inventions V and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different

inventions have different functions and are not disclosed to be used together. The kit of Group III contains antibodies to CD4 and CD45, the method of Group V does not require antibodies; therefore the method of Group V cannot be performed using the kit of Group III.

Inventions I, II and V are related to invention IV as processes and apparatus for their practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the methods of Groups I, II and IV could be performed manually, cells can be counted by visual inspection using a hemacytometer and separated using antibodies specific for the desired cell bound to magnetic beads, the processes do not need to be automated, therefore the methods do not require machine readable medium. Alternatively, if the methods are to be automated, and can all use the machine readable medium of Group IV, it is clear that the machine readable medium is not specific for any one method, as it can be modified to be used with any of the three distinct methods, as their distinctness was taught above.

Therefore, a search and examination of all inventions in one patent application would result in an undue burden. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and a search for one group does not require a search for another group, restriction for examination purposes as indicated is proper.

A telephone call was made to Mr. Alan Kopecki on 10 February 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M Ford whose telephone number is 571-272-2936. The examiner can normally be reached on M-F 7:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651

LEON B. LANKFORD, JR.
PRIMARY EXAMINER